

### **Remarks**

Claims 1-19 are pending.

#### Amendments

Claims 1 and 11 have been amended to clarify their scope and specify that the base parts and their associated coupling parts are made of the same material. Support for this amendment is found throughout the original specification and at least at page 3, lines 33-37. (“As a result of making the base part(s) and the coupling part(s) of one material, it is possible during manufacture to make use only of tools, which can be used to process the material employed.”)

Claim 9 have been amended remove the phrase “or both” to clarify that at least one of (i) the two base part or (ii) the coupling parts are at least partially coated. Likewise, claims 10, 18, and 19 have been amended to remove the phrase “or both”.

No new matter has been added.

#### Claim Rejection Under 35 U.S.C. § 112

Claims 8, 9, 18, and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 8 does not refer to “the base parts or the coupling parts being coated” or “both the base parts and the coupling parts being coated.” Thus, Applicant can only assume that the examiner intended to direct the rejection to claims 9, 10, 18, and 19. The rejection is respectfully traversed.

The Examiner asserts that the “recitation of the base parts or the coupling parts being coated, . . . and both the base parts and the coupling parts being coated” is indefinite. Applicant respectfully disagrees. One of ordinary skill in the art would understand, for example, that claim 9 encompasses embodiments wherein (i) the two base parts, (ii) the coupling parts, or (iii) both

the two base parts and the coupling parts are at least partially coated. The Examiner's assertion is based on misapplication of M.P.E.P. Section 2173.05(c) and the cited case law to Applicant's claims. M.P.E.P. Section 2173.05(c) is applicable to "Numerical Ranges and Amounts Limitations." Applicant's claims 9, 10, 18, and 19 do not include numerical limitations. Nor do Applicant's claims use the terminology "such as." Thus, the cited references, including *Ex parte Wu*, 10 U.S.P.Q.2d 2031 (1989), are not applicable to Applicant's claims. A person of ordinary skill in the art would understand that Applicant's claims recite what is required, and not what is exemplary. Though Applicant believes claims 9, 10, 18, and 19 to be clear and definite, Applicant has amended claims 9, 10, 18, and 19 to remove the phrase "or both" in order to advance prosecution. For the foregoing reasons, Applicant respectfully submits that the rejection should be withdrawn.

Claim Rejection Under 35 U.S.C. § 102

Claims 1-7, 9-16, 18, and 19 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication No. 2004/0243241 A1 to Istephanous et al. ("Istephanous"). The rejection is respectfully traversed.

Istephanous does not disclose all the elements of Applicant's claims. In particular, Istephanous does not disclose base parts and their associated coupling parts that are formed in one piece and made of the same material, which is a material selected from polyetherketone (PEK), polyetheretherketone (PEEK), polyacryletherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneethexketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK), as required by Applicant's claims.

Instead, Istephanous discloses that “[a]t least, the trough portion 74 of the third surface 72 [of the lower portion 54 of the spinal implant] is formed of a metal matrix composite that exhibits enhanced wear characteristics.” (Paragraph [0069]). No alternative materials for the trough 74 are disclosed by Istephanous. Therefore, according to Istephanous the trough 72 can only be formed of a metal matrix composite. This disclosure results in two alternatives: (1) the trough 74 and the lower portion 54 are both formed of a metal matrix composite; or (2) the trough 74 is formed of a metal matrix composite and the lower portion 54 is formed of a different biocompatible material. Thus, the first alternative of Istephanous lacks Applicant’s claimed materials, and the second alternative of Istephanous lacks base parts and their associated coupling parts being formed of one piece and made of the same material.

Therefore, Istephanous does not anticipate Applicant’s claims.

#### Claim Rejection Under 35 U.S.C. § 103

Claims 8 and 17 are rejected under 35 U.S.C. § 103(a) as obvious over Istephanous in view of U.S. Patent No. 6,322,588 B1 to Ogle et al. (“Ogle”). The rejection is respectfully traversed.

#### *Applicant's Claimed Prosthesis*

The materials specified by Applicant’s claims, PEK, PEEK, PAEK, PEKK, PEKEKK, and PEKEK, have similar moduli of elasticity to that of cortical bone. Thus, prosthesis parts comprising these polymeric materials avoid predetermined breaking points between the prosthesis and the bones, which occur when materials with different moduli of elasticity are used in combination. In addition, the prosthesis can be simply and efficiently produced because its parts are formed in one piece of the same material.

*Istephanous and Ogle*

As discussed above and in the previous response, Istephanous teaches away from modification of the implant disclosed to obtain a prosthesis in the precise fashion claimed by Applicant. Specifically, Istephanous teaches that the implants, and particularly the trough portion 74, should be made of a metal matrix composite. There is no hint or guidance in Istephanous for one skilled in the art to form the base parts and the coupling parts in one piece from the same polymeric material, as claimed by Applicant.

Nothing in Ogle, alone or in combination with Istephanous, can be construed to supplement this deficiency.

Thus, a *prima facie* case of obvious has not been established and Applicant's claims are novel and nonobvious.

**CONCLUSION**

The foregoing is believed to be a full response to the Office Action. In the event that any additional fees are required, the Patent Office is hereby authorized to charged Deposit Account No. 19-5029. If there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited to call the undersigned attorney at (404) 853-8036.

Respectfully submitted,



Kar Yee Tse  
Reg. No. 58,702

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SUTHERLAND ASBILL & BRENNAN LLP  
999 Peachtree Street, NE  
Atlanta, GA 30309-3996  
(404) 853-8036 (phone)  
(404) 853-8806 (facsimile)